

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

American Insurance Company, a Nebraska Corporation,)	Court File No. _____
)	
Plaintiff,)	
)	
v.)	<u>COMPLAINT FOR DECLARATORY</u>
)	<u>RELIEF</u>
St. Jude Medical, Inc.,)	
a Minnesota Corporation,)	
)	
Defendant.)	

Plaintiff American Insurance Company by and through its attorneys, Hinshaw & Culbertson LLP, for its Complaint for Declaratory Relief, states and alleges as follows:

JURISDICTION AND VENUE

1. Plaintiff American Insurance Company ("AIC") is a company incorporated in the State of Nebraska, with its principal place of business in Novato, California.

2. Defendant St. Jude Medical, Inc. ("SJM") is a company incorporated in the State of Minnesota with its principal place of business in St. Paul, Minnesota.

3. This Court maintains jurisdiction over this action pursuant to 28 U.S.C. § 1332. There is diversity of citizenship between the parties and the amount in controversy, exclusive of interest and costs, exceeds Seventy-Five Thousand Dollars (\$75,000).

4. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391.

JURY DEMAND

5. AIC demands a jury trial of any factual issues pursuant to Rule 38 of the Federal Rules of Civil Procedure.

BACKGROUND

The Silzone Valve Litigation

6. SJM manufactures a variety of medical devices including prosthetic heart valves. SJM has been named as a defendant in hundreds of legal actions brought in the United States, Canada, Europe, the United Kingdom and Australia arising out of alleged defects in a Silzone coated prosthetic heart valve ("Silzone valve"). In this Complaint the litigation arising out of alleged defects in the Silzone valve will be referred to as the "Underlying Litigation".

7. Some of the plaintiffs in the Underlying Litigation allege that they or their decedents sustained actual physical injury as a result of the alleged defects in the Silzone valve. These plaintiffs allege that they were injured as a result of a sudden, catastrophic failure of the Silzone valve.

8. Many of the plaintiffs in the underlying action are not seeking to recover damages for any physical injury that they sustained. The plaintiffs in these actions are seeking injunctive relief and damages based on false representations that allegedly were or should have been made by SJM in marketing the Silzone valves.

9. On information and belief, beginning in July of 1997, SJM introduced Silzone valves in Canada, Europe and the United Kingdom.

10. On information and belief, on March 24, 1998, the Silzone valve was approved by the FDA for commercial distribution in the United States.

11. On information and belief, in April of 1998, SJM began marketing the Silzone valve in the United States.

12. On information and belief, in June of 1998, SJM began selling the Silzone valve in the United States and Australia.

13. On information and belief, SJM sold approximately 60,000 Silzone valves which were implanted into citizens or residents of the United States, Canada, Europe, the United Kingdom and Australia.

14. On information and belief, SJM contended that the use of Silzone on the heart valves it manufactured would reduce the incidence of a post surgical infection of the heart known as Endocarditis. On information and belief, in order to obtain data to support its contention that the use of Silzone would reduce the incidence of Endocarditis, SJM sponsored a study known as the Artificial Valve Endocarditis Reduction Trial ("AVERT").

15. On information and belief, AVERT was a multi-national clinical trial designed to determine whether or not the Silzone valve actually reduced the incidence of Endocarditis.

16. On information and belief, on or about January 21, 2000, SJM announced to the public that further enrollment in the AVERT study would be suspended based upon the detection of an unacceptable number of incidents of paravalvular leakage ("PVL") involving patients who had received the Silzone valve.

17. On or about January 21, 2000, SJM initiated a voluntary recall of all un-implanted Silzone products, ceased all distribution of products with Silzone coating and discontinued the use of this technology.

18. On information and belief, some time after January of 2000, SJM notified hospitals and physicians, instructing them not to use Silzone products. On information and belief, letters were sent to physicians providing instructions on the care and management of patients with implanted Silzone valves. On information and belief, SJM did not recommend explants of its products with Silzone coating unless routine patient monitoring detected specific

complications. On information and belief, SJM did not advise any health professional that the Silzone valve presented a risk of "bodily injury."

19. After SJM instituted the voluntary recall, numerous lawsuits were filed against SJM. Several class actions were filed in the United States, many of which were consolidated for pretrial proceedings in this District pursuant to the Judicial Panel on Multidistrict litigation ("MDL") before Judge Tunheim.

20. Three class actions were also filed in Canada and are currently pending.

21. The Plaintiffs in the MDL seek damages for strict liability, breach of implied and express warranties, negligence and medical monitoring. The Plaintiffs in the MDL also seek relief under various Minnesota consumer statutes – the False Advertising Act, the Consumer Fraud Act, the Unlawful Trade Practices Act, and the Uniform Deceptive Trade Practices Act.

22. Through an order dated October 13, 2006, Judge Tunheim granted the Plaintiffs' renewed motion for certification of a Consumer Protection Class in MDL No. 1396, *In Re St. Jude Med., Silzone Heart Valves Products Liability Litigation ("In re Silzone")*. The Consumer Protection Class consists of more than 11,000 individuals described as: all prosthetic heart valve patients in the United States who have not undergone an explant of their Silzone valve or developed a manifest and diagnosed injury from their Silzone implant of degree or severity that would permit individual personal injury lawsuits to be commenced in their State of residence."

23. Judge Tunheim's certification order is on appeal to the United States Court of Appeals for the Eighth Circuit.

24. The *In re Silzone* Plaintiffs claim that St. Jude rushed the Silzone valve to market and failed to disclose:

- ☐ animal studies that revealed evidence of paravalvular leak and silver leaching;
- ☐ findings that Silzone caused hemolysis;

- evidence that the silver coating wore away after a short period of time;
- reports from the field and the AVERT study of little or no necessary tissue ingrowth on the Silzone valves;
- reports of a statistically significant increase in Silzone explants; and
- evidence that Silzone was not effective in fighting bacteria in animal studies.

25. The *In re Silzone* Plaintiffs allege that SJM rushed the Silzone valve to market and failed to ensure that the valves had been adequately tested or proven to be safe prior to market release.

26. The *In re Silzone* Plaintiffs allege that SJM deliberately ignored the adverse findings and warnings of its own consultants.

27. The *In re Silzone* Plaintiffs allege that SJM intentionally suppressed data and other information that would have been relevant to the regulators responsible for deciding to allow the sale of the Silzone valves.

28. Under Judge Tunheim's Order on the Motion for Class Certification in *In re Silzone*, the Consumer Protection Class can pursue the remedies provided by the Minnesota Prevention of Consumer Fraud Act ("MPCFA") and the Minnesota Uniform Deceptive Trade Practices Act ("MDTPA").

29. To prevail under the MPCFA, the Class must prove that SJM committed an act, use, or employment by fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice; and SJM intended that others would rely on the statements or practices in connection with the sale of the valves.

30. The individual class members in *In re Silzone* cannot recover damages under the MPCFA for any bodily injury they may have sustained as a result of the implantation of the Silzone valve.

31. To prevail under the MDTPA, the Consumer Protection Class must prove that SJM engaged in a deceptive trade practice by representing that the valves had sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they did not have; or representing that the valves were of a particular standard, quality, or grade or that they were of a particular style or model, which they were not.

32. The individual class members in *In re Silzone* cannot recover damages under the MPTPA for any bodily injury they may have sustained as a result of the implantation of the Silzone valve.

The AIC Insurance Coverage

33. For the policy period January 31, 1999 through January 31, 2000, AIC provided excess liability insurance coverage to SJM through policy number XXX-000-9610-6778. A true and correct copy of policy number XXX-000-9610-6778 is attached as Exhibit A to this Complaint. In this Complaint, policy number XXX-000-9610-6778 will be referred to as the "AIC policy." The AIC policy provided \$50 million dollars of coverage in excess of \$150 million in underlying self-insurance/insurance.

34. The defense and indemnity of SJM in the Silzone litigation is currently being handled by the immediate underlying layer of excess coverage provided by Chubb Custom Insurance Company, Northfield Insurance Company and TIG Specialty Insurance Company. This layer of coverage provides \$40 million dollars in limits. On information and belief, the available limits of liability under the immediate underlying layer will be exhausted in the immediate future.

35. After the underlying layer of insurance is exhausted SJM has advised AIC that it expects AIC to pay both defense and indemnity incurred in the Underlying Litigation.

36. The AIC policy incorporates the following insuring agreement:

INSURING AGREEMENTS

I. COVERAGE.

Subject to the other provisions of this policy, **We** will indemnify the Insured for the Insured's **Ultimate Net Loss** if such loss results from an occurrence insured by all of the policies designated in the declarations as **Underlying Insurance**. However, the insurance afforded by this policy shall apply (a) only in excess of all **Underlying Insurance**, and (b) only after all **Underlying Insurance** has been exhausted by payment of the limits of such insurance. If any **Underlying Insurance** does not pay a loss, for reasons other than exhaustion of an aggregate limit of insurance, then **We** shall not pay such a loss.

The definitions, terms, conditions, limitations, exclusions, and warranties of the "first **Underlying Insurance**" policy, in effect at the inception date of this policy, apply to this coverage unless they are inconsistent with provisions of this policy, or relate to premium, subrogation, an obligation to investigate and defend, the amount of limits of insurance, payment of expenses, cancellation or any renewal agreement.

37. The AIC policy defines "Underlying Insurance" to mean:

The policy or policies of insurance scheduled in item 7 of the Declarations, including their Extended Reporting Period(s), if provided.

38. Pursuant to the insuring agreement, the AIC policy incorporates certain definitions, terms, conditions, limitations, exclusions, and warranties of the "first **Underlying Insurance**".

39. For the policy period January 31, 1999 – January 1, 2000 the first Underlying Insurance was provided by MEDMARC Casualty Insurance Company through policy number 99MN380003 ("the MEDMARC policy"). A true and correct copy of the MEDMARC policy is attached as Exhibit B.

40. The AIC policy does not incorporate any provision of the MEDMARC policy that relates to premium, subrogation, an obligation to investigate and defend, the amount of limits of insurance, payment of expenses, cancellation or any renewal agreement.

41. The AIC policy does not incorporate any provision of the MEDMARC policy that is inconsistent with any provision of the AIC policy.

42. The AIC policy expressly provides that AIC does not have a duty to defend. AIC's obligation to pay defense and expenses is controlled by the following provision:

II. DEFENSE AND EXPENSE OF CLAIMS AND SUITS.

A. **We** shall not be obligated to assume charge of or participate in the settlement or defense of any claim made, or suit brought, or proceedings instituted against the Insured. However, **We** shall have the right and opportunity to be associated with the Insured in the defense of any claim, suit or proceeding which, in **Our** opinion, may create liability under the terms of this policy. If **We** assume such right and opportunity, **We** shall not continue to defend or participate in the defense of any claim or suit after the applicable limit of this policy has been exhausted.

B. **We** shall not pay any expenses except as follows:

- (1) If the Insured is legally liable for interest which accrues on a judgment after the entry of the judgment and before **We** have paid, offered to pay, or deposited in the court the amount of the judgment to which this policy applies, then **We** will pay the interest on the amount of the judgment to which this policy applies.
- (2) If an expense is incurred directly by **Us** and solely at **Our** discretion, then **We** will pay such expense.
- (3) If a payment for damages is made under this policy, then **We** will pay related prejudgment interest for which the Insured is legally liable, provided :

* * *

43. AIC has no obligation to pay any defense expenses incurred by SJM in the Underlying Litigation. AIC's only obligation is to pay those defense expenses it incurs directly if and when it exercises its right to associate in the defense of a claim or suit seeking covered damages.

44. The MEDMARC policy incorporates the following insuring agreement:

1. Insuring Agreement

a. We will pay those sums that the insured becomes legally obligated to pay as damages because of "bodily injury" or "property damage" included within the "products-completed operations hazard" to which this insurance applies. We will have the right and duty to defend the insured against any "suit" seeking those damages. However, we will have no duty to defend the insured against any "suit" seeking damages for "bodily injury" or "property damage" to which this insurance does not apply. We may, at our discretion, investigate any "occurrence" and settle any claim or "suit" that may result. But:

- (1)** The amount we will pay for damages is limited as described in LIMITS OF INSURANCE (Section **III**); and
- (2)** Our right and duty to defend does not begin until the applicable limit of your self-insured retention has been used up in the loss reserves and payment of judgments, settlements and defense expenses; and
- (3)** Our right and duty to defend end when we have used up the applicable limit of insurance in the payment of judgments, settlement and defense expenses.

No other obligation or liability to pay sums or perform acts or services is covered unless explicitly provided for under SUPPLEMENTARY PAYMENTS.

45. Upon information and belief, the term "bodily injury" was defined in the MEDMARC policy as follows:

"Bodily injury" means bodily injury, sickness or disease sustained by a person, including death resulting from any of these at any time.

46. The term "occurrence" was defined by the MEDMARC policy as follows:

11. "Occurrence" means an accident, including continuous or repeated exposure to substantially the same general harmful conditions.

As regards, "Products-completed operations hazard" and with respect to "bodily injury" or "property damage," the date of "occurrence" is deemed to be the earlier date of:

- a.** a claim is made or "suit" is brought alleging injury or damage resulting from your product;

* * *

- g.** the date of the advisory memorandum initiated by you. An "advisory memorandum" is any communication issued by you to inform health professionals or other appropriate persons or firms of a risk of substantial harm from a product in commercial use.

(Exhibit B)

47. The MEDMARC policy describes where a claim will be deemed to have first been made, in relevant part, as follows:

- c.** A claim by a person or organization seeking damages will be deemed to have been made at the earlier of the following times:
 - (1)** When notice of such claim is received and recorded by any insured or by us, whichever comes first; or
 - (2)** When we make settlement in accordance with paragraph **1.a.** above.

All claims for damages because of "bodily injury" to the same person, including damages claimed by any person or organization for care, loss of services, or death resulting at any time from the "bodily injury", will be deemed to have been made at the time the first of those claims is made against any insured.

(Exhibit B)

48. On information and belief no advisory memorandum informing health professionals of a risk of substantial harm from the Silzone valve was issued prior to January 31, 2000, the expiration date of the MEDMARC policy and the AIC policy.

49. The MEDMARC policy expressly provided that coverage only applies to claims for "bodily injury" which were made prior to the expiration date of the policy (January 31, 2000) and after the Retroactive Date of the policy (December 18, 1987) as follows:

- b.** This insurance applies to "bodily injury" and "property damage" only if:
 - (1)** The "bodily injury" or "property damage" is caused by an "occurrence" that takes place in the "coverage territory";
 - (2)** The "bodily injury" or "property damage" did not occur before the Retroactive Date, if any, shown in the Declarations or after the end of the policy period; and

- (3) A claim for damages because of "bodily injury" or "property damage" is first made against any insured, in accordance with paragraph c. below, during the policy period or any Extended Discovery Period we provide under EXTENDED DISCOVERY PERIODS (Section V).

50. The MEDMARC policy provided coverage on a "claims made" basis. The AIC policy incorporated the following provision that describes when the injury or damage must occur to fall within the coverage where the underlying insurance applies on a "claims made" basis:

Claims-Made

If the coverage provided by the "first **Underlying Insurance**" applies on the basis of aims first made against the Insured during the period of that policy, then this coverage only applies to those claims on the same basis and in a like manner; provided the date such aim is first made against the Insured is during **Our** policy period, and the injury or damage takes place on or after the Retroactive Date shown in **Our** Declarations, and prior the termination of the policy.

51. The retroactive date of the MEDMARC policy and the AIC policy is December 18, 1987. The expiration date of the AIC policy is January 31, 2000. On information and belief some of the claimants and plaintiffs in the Underlying Litigation seek damages for an injury that took place after January 31, 2000.

52. The MEDMARC policy incorporates the following provision:

BATCH CLAUSE

SECTION VI – DEFINITIONS, the term "occurrence" with respect to "products-completed operations hazard" is amended to include the following:

The term "batch" means all products which have the same known or suspected defect or deficiency which is identified by the same advisory memorandum.

The term, "advisory memorandum" is any communication issued by you to inform health professionals or other appropriate persons or firms of a risk of "bodily injury" or "property damage" from a product in use.

Coverage does not apply to any loss, claim or "suit" which arises out of a defect or deficiency which was known or suspected prior to the retroactive date shown in this policy.

When this endorsement is attached to your policy, all losses arising from a single "batch" of your product will be considered to be one "occurrence." Therefore, when multiple losses are considered to be on "occurrence" you must only meet a single "self insured retention" amount. Likewise, our limit of liability due to "bodily injury" and "property damage" is limited to that of a single "occurrence".

All claims made by persons or organizations seeking damages because of "bodily injury" or "property damage" arising out of one batch will be deemed to have been made at the time the first of those claims is made against you.

(Exhibit B)

53. On information and belief, SJM never issued an advisory memorandum describing a known or suspected defect or deficiency in the Silzone valve informing health professionals of a risk of "bodily injury" attributable to the Silzone valve. The "batch clause" does not apply to the claims that have been made in the Silzone litigation. If a "claim" arising out of "bodily injury" resulting from the Silzone implant was not first made during the period January 31, 1999 – January 31, 2000 it will not be covered by the MEDMARC policy or the AIC policy.

54. The AIC policy incorporates the following exclusion:

This insurance does not apply to:

a. Expected or Intended Injury

"Bodily injury" or "property damage" expected or intended from the standpoint of the insured . . .

55. There is no coverage under the AIC policy for any damages awarded as a result of fraud and/or other intentional conduct.

THE DISPUTE

56. AIC realleges and incorporates by reference the allegations set forth in paragraphs 1 – 55 of the Complaint.

57. A real and justiciable controversy exists between AIC and SJM.

58. AIC contends that it has no duty to defend the Underlying Litigation and no obligation to pay or reimburse SJM for any defense incurred by SJM in defending the Underlying Litigation. On information and belief, SJM disputes AIC's contention that it has no duty to defend the Underlying Litigation and no obligation to pay or reimburse SJM for any defense incurred by SJM in defending the Underlying Litigation.

59. AIC contends that it has no duty to pay any damages attributable to "bodily injury" sustained by any recipient of a Silzone implant after January 31, 2000. On information and belief, SJM disputes AIC's contention that it has no duty to pay any damages attributable to "bodily injury" sustained by any recipient of a Silzone implant after January 31, 2000.

60. AIC contends that it has no duty to pay any damages attributable to a claim or suit arising out of a Silzone implant that was not first made and reported to AIC during the period January 31, 1999 – January 31, 2000. On information and belief, SJM disputes AIC's contention that it has no duty to pay any damages attributable to a claim or suit arising out of a Silzone implant that was not first made and reported to AIC during the period January 31, 1999 – January 31, 2000.

61. AIC contends that it has no duty to pay for any relief or damages that may be awarded to the Consumer Protection Class in *In re Silzone*. On information and belief, SJM disputes AIC's contention that it has no duty to pay for any relief or damages that may be awarded to the Consumer protection Class in *In re Silzone*.

62. AIC contends that it has no duty to pay amounts incurred by SJM in continuing to fund the AVERT study. On information and belief, SJM disputes AIC's contention that it has no duty to pay amounts incurred by SJM in continuing to fund the AVERT study.

COUNT ONE-DECLARATORY RELIEF

63. AIC realleges and incorporates by reference the allegations set forth in paragraphs 1 – 62 of the Complaint.

64. AIC seeks a declaration that it has no duty to defend the Underlying Litigation and no obligation to pay or reimburse SJM for any defense incurred by SJM in defending the Underlying Litigation.

65. AIC seeks a declaration that it has no duty to pay any damages attributable to "bodily injury" sustained by any recipient of a Silzone implant after January 31, 2000.

66. AIC seeks a declaration that it has no duty to pay any damages attributable to a claim or suit arising out of a Silzone implant that was not first made and reported to the Company during the period January 31, 1999 – January 31, 2000.

67. AIC seeks a declaration that it has no duty to pay for any relief or damages that may be awarded to the Consumer Protection Class in *In re Silzone*.

68. AIC seeks a declaration that it has no duty to pay amounts incurred by SJM in continuing to fund the AVERT study.

RELIEF REQUESTED

WHEREFORE, AIC respectfully requests that this Court find and declare that:

1. AIC has no duty to defend the Underlying Litigation and no obligation to pay or reimburse SJM for any defense incurred by SJM in defending the Underlying Litigation.

2. AIC has no duty to pay any damages attributable to "bodily injury" sustained by any recipient of a Silzone implant after January 31, 2000.

3. AIC has no duty to pay any damages attributable to a claim or suit arising out of a Silzone implant that was not first made and reported to the Company during the period January 31, 1999 – January 31, 2000.

4. AIC has no duty to pay for any relief or damages that may be awarded to the Consumer protection Class in *In re Silzone*.

5. AIC seeks a declaration that it has no duty to pay amounts incurred by SJM in continuing to fund the AVERT study.

6. And grant such other, further, or different relief as the Court deems just and equitable.

Dated: January 2, 2008

Respectfully submitted,

s/ Duana J. Grage

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